

**Remarks/Arguments:**

**Preliminary Matters:**

Applicants hereby affirm the election made, without traverse, to prosecute the invention of Group I, Species A, claims 1 - 8, 10, 11, 17, 30 - 33, and 47 during a telephone conversation between the Examiner and Rex Donnelly on May 17, 2004.

Claims 1, 3 - 8, 10, 11, 17, 30 - 33, and 47 are pending, new claim 51 has been added, and claim 2 has been canceled without prejudice or disclaimer of the subject matter thereof.

**35 U.S.C. § 112**

Claim 32 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 32 has been amended and claim 51 has been added to clarify the claim language. Applicants contend that no new matter has been added. Reconsideration of these claims is respectfully requested.

**35 U.S.C. § 102**

Claims 1, 10, 11, 30, and 32 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,201,757 to Heyn et al. Applicants respectfully traverse this rejection and respectfully submit that these claims are patentable over Heyn for the reasons set forth below.

Independent claim 1, as amended, recites at least one feature that is neither disclosed nor suggested by Heyn, namely:

...anchoring means in at least one of the retrograde portion or the anterograde portion for anchoring the proximal end of the endoluminal device in the body lumen to minimize relative axial movement between the proximal end of the device and the body lumen during deployment of the device from the device proximal end toward the device distal end.

By way of example, as shown in the embodiment depicted in Applicants' Figs. 2 and 7 wherein the proximal end 131 and balloon 120 are located under anterograde sheath 126, the anterograde sheath 126 is initially advanced far enough to expose the proximal end 131 and balloon 120 (i.e., *anchoring means*). Balloon 120 is inflated in step 240 to exert radial force that compresses the retrograde portion 133 of device 130 against the lumen wall (not shown). In other words, the anchoring means 120 prevents any substantial axial travel of the endoluminal device 130 relative to the body lumen during deployment of the device from the device proximal end toward the device distal end. The anchoring means feature for anchoring the device in the body lumen during deployment of the device is found in the originally filed application at page 9, lines 10 - 14. No new matter has been added.

In contrast, Heyn discloses a stent deployment device 74 that incorporates an intermediate catheter 100 contained within lumen 80 of outer catheter 76 and surrounding inner catheter 78. Column 6, lines 48 – 50. As illustrated in Fig. 2, annular detents 102 and 104, surrounding and secured to catheter 100 on opposite sides of a radially self-expanding stent 106, prevent any substantial axial travel of *the stent 106 relative to the intermediate catheter 100* during deployment of the device *from its midsection toward its ends*. Column 6, lines 50 – 54. Heyn neither discloses nor suggests an anchoring means for anchoring the proximal end of the device *in the body lumen* to minimize relative movement between the proximal end and the lumen during deployment of the device from its proximal end toward its distal end. Heyn only shows a structure for anchoring the ends of a device relative to an intermediate sheath and for deployment of a device from its middle toward its ends. Furthermore, the structure shown in Heyn does not have the same functional characteristics as the structure claimed by Applicants.

Accordingly, for the foregoing reasons, Applicants respectfully submit that independent claim 1 (as amended) is patentable over Heyn and should be allowed. Claims 10, 11, 30, and 32 are dependent upon claim 1, and therefore should also be allowed at least as dependent upon an allowable base claim.

**35 U.S.C. § 103**

**Heyn in View of Marianne**

Claims 3 - 6 and 47 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Heyn in view of U.S. Patent No. 6,042,589 to Marianne. Applicants respectfully traverse this rejection and respectfully submit that these claims are patentable over Heyn in view of Marianne for the reasons set forth below.

Marianne discloses a delivery device 1 including a chamber 6 (with a stent 7 inserted therein) extending around an inner tube 8. Column 2, lines 48 - 52. As illustrated in Fig. 2, a micro-balloon 20 is slightly inflated, causing the proximal end of the stent 7 to be firmly locked in place *with respect to the inner tube 8*. Column 3, lines 6 - 9. Marianne neither teaches nor suggests an anchoring means for anchoring the proximal end of the device *in the body lumen* during deployment of the device from its proximal end toward its distal end. Marianne only shows an introducer adapted for deployment of a device from the device distal end toward the device proximal end and for use of a balloon to fix the proximal end relative to the inner tube or to move the device relative to the lumen after deployment. There is no suggestion to modify Marianne, or the combination of Heyn plus Marianne, to arrive at Applicants' claimed invention.

Thus, because claim 1 includes limitations that are neither disclosed nor suggested by Heyn or Marianne, alone or in combination, *prima facie* obviousness cannot be established based on the cited references. Accordingly, Applicants respectfully submit that claims 3 - 6, which are dependent upon claim 1, should be allowed.

Independent claim 47, while not identical to claim 1, includes features similar to claim 1. Specifically, among other things, claim 47, as amended, recites an introducer for deployment of an endoluminal device *in a body lumen* in a distal location from a proximal location, the introducer comprising a retrograde portion, an antegrade portion, a shaft, an endoluminal device, and *an inflatable balloon* mounted radially inside the retrograde portion *for anchoring the endoluminal device in the body lumen* during deployment of the device. Accordingly, it is respectfully submitted that claim 47 is also patentable over the proposed combination of Heyn and Marianne, and should be allowed.

**Heyn as Modified by Marianne**

Claims 7, 8, and 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Heyn as modified by Marianne. Applicants respectfully traverse this rejection and respectfully submit that claims 7, 8, and 17, which are dependent upon claim 1, are patentable over Heyn as modified by Marianne for the reasons set forth above with respect to claims 3 - 6.

**Heyn in View of Euteneuer**

Claims 31 and 33 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Heyn in view of U.S. Patent No. 5,445,646 to Euteneuer et al. Applicants respectfully traverse this rejection and respectfully submit that these claims are patentable over Heyn in view of Euteneuer for the reasons set forth below.

Euteneuer discloses a delivery system for implantation of a self-expanding stent in a vessel. Euteneuer is cited in the Office Action only for its teaching of the antegrade sheath covering more than the retrograde sheath and for overlapping the two sheaths. Euteneuer neither teaches nor suggests *an anchoring means for anchoring the proximal end of the device in the body lumen* to minimize relative axial movement between the proximal end of the device and the body lumen during deployment of the device.

Thus, because claim 1 includes limitations that are neither disclosed nor suggest by Heyn or Euteneuer, alone or in combination, claims 31 and 33, which are dependent upon claim 1, should be allowed.

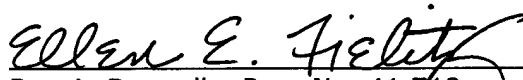
Appln. No.: 10/081,641  
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BSI-486US

**Conclusion:**

In view of the amendments and points of distinction set forth above, Applicants contend that the above-identified application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

  
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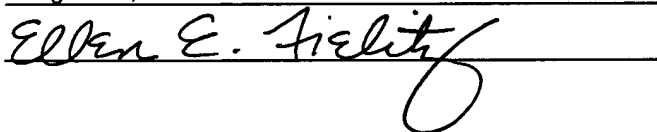
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